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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,130	08/08/2006	Richard Twomey	DEP5008	6010

27777 7590 07/16/2007  
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EXAMINER
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SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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07/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/564,130

**Applicant(s)**

TWOMEY ET AL.

**Examiner**

Ann Schillinger

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/12/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

Claims 2-19 are objected to because of the following informalities: they are dependent claims using indefinite articles, when definite articles should be used. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

Claims 4 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 4, it is unclear if the “internal cavity” of claim 1 and the “opening” of claim 4 are the same structures, as there is only one sleeve opening disclosed in the specification. Claim 12 claims additional surface features to promote the plug’s engagement with the bone. However, claim 1 requires that the outer surface of the sleeve be “circumferentially continuous,” which according to its definition, means the surface has no breaks or irregularities, thus contradicting the limitations of claim 12 (continuous. Dictionary.com. *WordNet*® 3.0. Princeton University. <http://dictionary.reference.com/browse/continuous> (accessed: July 06, 2007)).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8, 13, 17, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Mastrorio et al. (US Pat. No. 5,997,580). Mastrorio et al. discloses the following of claim 1: a bone cement plug for fitting into the intramedullary canal within a bone to restrict flow of bone cement during surgery, which comprises: a. a sleeve (60) whose wall is circumferentially continuous and has an outer surface for contacting the wall of the canal, and whose inner surfaces define an internal cavity and the longitudinal axis of the sleeve, the sleeve being formed from a deformable material so that it can be expanded transversely to contact the surface of the canal (see Figures 19, 20; col. 6, lines 40-55), b. an expander (62, 64) which can be drawn through the cavity in a direction generally along the axis of the sleeve, to cause the sleeve to expand transversely to contact the surface of the canal (col. 7, lines 29-40), in which the inner surfaces of the wall converge towards the end of the sleeve towards which the expander is drawn to cause the sleeve to expand to contact the surface of the canal (see Figures 19, 21).

Mastrorio et al. discloses the limitations of claims 2, 3, and 13 as shown in Figures 19-21.

Mastrorio et al. discloses the following of claims 4 and 8: a bone cement plug as claimed in claim 2, in which the end wall of the sleeve has an opening (central opening of 60) extending through it, and in which the expander comprises a shaft (62) which extends generally along the sleeve axis, and a transverse portion (64) which contacts the internal wall of the cavity in the sleeve, the shaft extending through the opening in the end wall of the sleeve to that it can be engaged to draw the expander through the sleeve. Please note that the examiner is interpreting the opening to be the same feature as the internal cavity of claim 1.

Mastrorio et al. discloses the instrument of claim 17 in element 38.

Mastrorio et al. discloses the limitations of claim 19 in col. 7, lines 29-40.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrorio et al. in view of Spierings (US Pat. No. 6,669,733). Mastrorio et al. discloses the invention substantially as claimed, however, Mastrorio et al. probably does not disclose an expander where the shaft can break. Spierings teaches an expander where the shaft can break in col. 4, lines 25-40 for the purpose of causing the maximum compression force on the body to obtain a strong fixation of the prosthesis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an expander where the shaft can break in order to cause the maximum compression force on the body to obtain a strong fixation of the prosthesis.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrorio et al. in view of Rybicki et al. (US Pat. No. 4,011,602). Mastrorio et al. discloses the invention substantially as claimed, however, Mastrorio et al. probably does not disclose including washers with the expander. Rybicki et al. teaches disclose including washers with the expander in col. 5, line 23 through col. 6, line 37 for the purpose of securing the expander and the plug. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use washers with the expander in order to secure the expander and the plug.

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Claims 9 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrorio et al. in view of Evans et al. (US Pat. No. 7,156,880). Mastrorio et al. discloses the invention substantially as claimed, however, Mastrorio et al. probably does not disclose using resorbable materials. Evans et al. teaches using resorbable materials in col. 25, lines 33-61 for the purpose of leaving a larger effective porosity. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use resorbable materials in order to leave a larger effective porosity.

Claims 10, 11, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrorio et al. Mastrorio et al. discloses the invention substantially as claimed, however, Mastrorio et al. probably does not disclose the angles of expansion and the specific material hardness measurements disclosed by the Applicant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use these values, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrorio et al. in view of Weber (US Pat. No. 4,447,915). Mastrorio et al. discloses the invention substantially as claimed, however, Mastrorio et al. probably does not disclose additional features on the surface of the sleeve. Weber teaches additional features on the surface of the sleeve in col. 2, lines 47-68 for the purpose of serving as anchors. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use additional features on the surface of the sleeve in order to serve as anchors.

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Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrorio et al. in view of Chan (US Pat. No. 5,935,169). Mastrorio et al. discloses the invention substantially as claimed, however, Mastrorio et al. probably does not disclose an instrument capable of holding the expander. Chan teaches an instrument capable of holding the expander in col. 5, line 60 through col. 8, line 51 for the purpose of properly guiding the expander and plug. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an instrument capable of holding the expander in order to properly guide the expander and plug.

### *Conclusion*


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger  
July 6, 2007

  
**ALVIN J. STEWART**  
**PRIMARY EXAMINER**